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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,202	11/05/2001	Alan H. Ostroff	032580.0045.CIP	7091

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,202

Applicant(s)

OSTROFF ET AL.

Examiner

Kristen Mullen (formerly
Droesch)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/21/04 (amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 150,153-159 and 162-165 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 150,154-156,164 and 165 is/are allowed.
- 6) ☐ Claim(s) 153,157-159,162 and 163 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/02/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims is withdrawn in view of the newly discovered reference(s) to Kroll et al. (5,514,160). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 153, 157-159, and 162-163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (5,230,337) in view of Kroll et al. (5,514,160).

Regarding claim 153, Dahl shows a method of treating a patient comprising: implanting a device having a housing (192) and containing circuitry for sensing and treating tachycardia, implanting at least one electrode (188, 190) coupled to the device for use in sensing or treating cardiac function of the patient, wherein the at least one electrode is implanted to be non-vascular and non-cardiac; sensing a portion of the patient's cardiac cycle, categorizing the patient's cardiac cycle as acceptable or abnormal; and if the cardiac cycle is abnormal, and generating a electric signal to treat the abnormal cardiac cycle between implanted non-vascular and non-cardiac electrodes (188, 190) (Fig. 22; Col. 3, line 61- Col. 4, line 9; Col. 9, line 52-Col. 10, line 6) Although Dahl et al. fails to show circuitry configured to provide a constant current output signal and generating a constant current electric signal, attention is directed to Kroll et al which teaches configured to provide a constant current output signal and generating a constant current signal (Fig 7D). Kroll et al. teaches that utilizing a rectangular waveform is advantageous because a

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larger fraction of energy initially stored in the capacitor is left in the capacitor and 65% as much energy is delivered in a defibrillation pulse compared to a conventional monophasic waveform (Col. 6, line 56-Col. 8, line 13). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Dahl et al. with circuitry configured to provide a constant current output signal and generating a constant current electric signal as Dahl et al. teaches since a larger fraction of energy initially stored in the capacitor is left in the capacitor and 65% as much energy is delivered in a defibrillation pulse compared to a conventional monophasic waveform.

With respect to claim 157, Dahl et al shows a method of treating a patient comprising implanting a device having a housing and containing circuitry for sensing and treating tachycardia, implanting at least one electrode (188, 190) coupled to the device for use in sensing or treating cardiac function of the patient, wherein the at least one electrode (188, 190) is implanted to be non-vascular and non-cardiac; sensing a portion of the patient's cardiac cycle, categorizing the patient's cardiac cycle as acceptable or abnormal; and if the cardiac cycle is abnormal, generating a electric signal to treat the abnormal cardiac cycle, the generated between implanted non-vascular and non-cardiac electrodes (188, 190) (Fig. 22; Col. 3, line 61- Col. 4, line 9; Col. 9, line 52-Col. 10, line 6). Although Dahl et al. fails to show circuitry configured to provide a constant current output signal and generating a constant current electric signal, attention is directed to Kroll et al which teaches configured to provide a constant current output signal and generating a constant current signal (Fig 7D). Kroll et al. teaches that utilizing a rectangular waveform is advantageous because a larger fraction of energy initially stored in the capacitor is left in the capacitor and 65% as much energy is delivered in a defibrillation pulse

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compared to a conventional monophasic waveform (Col. 6, line 56-Col. 8, line 13). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Dahl et al. with circuitry configured to provide a constant current output signal and generating a constant current electric signal as Dahl et al. teaches since a larger fraction of energy initially stored in the capacitor is left in the capacitor and 65% as much energy is delivered in a defibrillation pulse compared to a conventional monophasic waveform.

Regarding claim 158, Dahl et al. shows the lead system does not reside in the patient's vasculature (Fig. 22).

With respect to claim 159, Dahl et al shows the step of sensing an abnormality in the patient's cardiac rhythm makes use only of electrodes (188, 190) disposed outside of the patient's heart and vasculature (Col. 10, lines 3-6)

Regarding claim 162, Dahl et al shows the anode (188) and cathode (190) are on opposing sides of the heart (Fig. 22)

With respect to claim 163, Dahl et al shows the device and the lead system are disposed in the patient such that electrodes in the lead system consist of electrodes (188, 190) disposed outside of the patient's heart and vasculature (Fig. 22).

Allowable Subject Matter

4. Claims 150, 154-156, 164-165 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen (formerly Droesch) whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

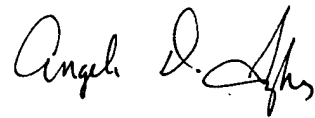
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



kdm



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